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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,947	08/07/2006	Untack Lee	44352-0009-00-US	8890
23973 7590 12/02/2008 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996				
EXAMINER				
CUTLIFF, YATE KAI RENE				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
12/02/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,947

Applicant(s)

LEE ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 28, 2008 & September 22, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1 - 11 are pending.
Claims 1 - 11 are rejected.

Response to Amendment

2. The amendment to Specification, submitted March 28, 2008 & September 22, 2008 is acknowledged and entered.
3. The amendment to claims 1 - 9, submitted September 22, 2008 is acknowledged and entered.
4. New claims 10 - 11, submitted September 22, 2008 are entered.

Response to Arguments

5. Applicant's arguments, see pages 7-8, filed March 28, 2008, and page 4 of September 22, 2008, with respect to the rejection(s) of claim(s) 1-9 under 35 U.S.C. 103(a) as obvious over Koike et al in view of Can have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection of claims 1-11 is made in view of Ilshinwells Co., Ltd. (WO 2004/096748 A1) in view of Cain et al. (US 6,184,009), in view of Kramer, Am. J. Clin. Nutr 2004) and further in view of Wikipedia (en.wikipedia.org/wiki/Fat), as set out below.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ilshinwells Co., Ltd. (WO 2004/096748 A1) in view of Cain et al. (US 6,184,009), in view

of Kramer, Am. J. Clin. Nutr 2004) and further in view of Wikipedia (en.wikipedia.org/wiki/Fat).

10. The rejected claims cover, inter alia, an oil composition comprising about 80-95% by weight of diglycerides, wherein about 5-98% of the fatty acids contained in the total triglycerides are a conjugated linoleic acid (CLA). The dependent claims disclose the weight percentage of the remaining portion of the oil composition; the isomeric forms of the CLA; the animal and vegetable oils used to obtain the CLA; and the uses for the CLA composition. Additionally, 75% of the fatty acids contained in the total triglycerides are CLA.

Ilshinwells discloses a fat composition comprising 85 to 99.9% high purity diglyceride which comprises 1-80% conjugated linoleic acid with the balance of the crude composition being composed of monoglyceride, triglyceride or fatty acids. (see abstract; paragraph [41] & Example 5, Table 2). Examples of oils and fats useful in the preparation of the fat composition include vegetable oils such as soybean and rapeseed oil. Ilshinwells' states that CLA are known to be in muscle ruminants. Further, the composition of Ilshinwells can be used as cosmetic emulsifiers, pharmaceutical emulsifiers and highly functional food additives having functions of effecting anticancer activity, reducing human body fat, enhancing immunogenicity, and treating diabetes.

Ilshinwells fails to state that the composition is an oil; disclose the isomeric formations of the CLA in the diglyceride composition; the use of the pharmaceutical composition of the CLA in tablets, capsule and powder form; and feedstuff additive.

However, Cain teaches a process for preparing a material containing the geometrical isomers of conjugated linoleic acid moieties in specific weight ratios, where the starting material is fish oil or vegetable oil and the products may be blended with complementary fat, used as food or food supplements or in pharmaceutical compositions. (see abstract). Further, Kramer discloses that many CLA isomers have been identified in natural products, mainly in fats from ruminants, ranging from 7,9 to 12,14-CLA, with each of the positional isomers occur as 4 geometric isomers (cis, trans; trans, cis; cis, cis; and trans, trans) for a total of 24. The most abundant CLA isomer in normal dairy and beef fats is c9,t11-CLA with smaller levels of t7,c9-CLA and t11,c13-CLA, depending on the diet. (page 1138S, column 1, last paragraph).

Furthermore, with regard to Ilshinwells' use of the term fat to describe their composition, it is known that the only main difference between a fat and oil is that a fat is a solid at room temperature, and the term fat usually refers to the collective term for "fats and oils". (see en.wikipedia.org/wiki/Fat page 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have an oil composition comprising 80 to 95% diglycerides by weight that contained 5 to 98% conjugated linoleic acid (CLA), as suggested by Ilshinwells, with the oil composition consisting of various geometric isomers of the CLA since Kramer discloses that there are 24 total known isomers of CLA and that Cain suggest a process for preparing the geometric isomers of CLA and produce the instant invention. One of ordinary skill in the art would have been

motivated to do this because CLA as suggested by Ilshinwells and Cain et al. have uses as foods, food supplements and pharmaceutical supplements.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With regard to Ilshinwells' failure to disclose the use of the pharmaceutical composition in a tablet, capsule and powder form. It is within the purview of the ordinary artisan that a pharmaceutical composition can be in a tablet, capsule or powder form, therefore, these limitations are deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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